

Doc Code: AP.PRE.REQ



PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 32286-192724	
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	First Named Inventor Richard J. Whitbourne		
	Art Unit 1618	Examiner Micah Paul Young	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number 31,957</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

Signature

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202.344.4072

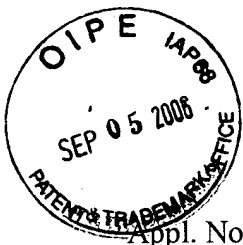
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No : 09/834,307  
Applicant : Richard J. Whitbourne et al.  
Filed : April 12, 2001  
Art Unit : 1618  
Examiner : Micah Paul Young

Confirmation No. : 3036

Docket No. : 32286-192724  
Customer No. : 26694

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Commissioner for Patents  
P.O. Box 1450  
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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

Claims 23-74 of the above-identified application have been finally rejected in the U.S. Patent and Trademark Office Action of March 2, 2006 ("2006 Action"). This Pre-Appeal Brief Request for Review of the above-identified application, filed with form PTO/SB/33 and a Notice of Appeal, pursuant to "New Pre-Appeal Brief Conference Pilot Program" (1296 Off. Gaz. Pat. Office 67 (July 12, 2005)) and "Extension of the Pilot Pre-Appeal Brief Conference Program" (1303 Off. Gaz. Pat. Office 21 (February 7, 2006)), presents Applicants' arguments for the allowability of the pending claims. Please charge the Notice of Appeal fee for a small entity of \$250.00 and any additional fees necessary to our Deposit Account No. 22-0261.

**I. Rejection of Claims 23-25, 28-52, 56-58, 61-65, 67-71, and 74 over Whitbourne '483**

In items 3-7 on pages 2-4 of the Office action of March 2, 2006 pertaining to the above-identified application ("2006 Action"), the Examiner rejects claims 23-25, 28-52, 56-58, 61-65, 67-71, and 74 under 35 U.S.C. § 103(a) as being unpatentable over the disclosures of U.S. Patent Number 6,110,483 to Whitbourne et al. ("Whitbourne '483"). The Examiner has not satisfied either of the criteria required to establish a *prima facie* case of obviousness. The prior art reference cited by the Examiner does not teach or suggest all the claim limitations; and the Examiner has presented no suggestion or motivation, either in the reference or in the knowledge generally available in the art, to modify the reference or combine reference teachings. *See e.g.* MPEP 2142.

**A. Lack of Teaching or Suggestion of All the Claim Limitations**

Independent claims 23, 43, 45, 61, and 68 each include the limitation "a coating ... bridging from one edge or surface to another." Similarly, independent claim 50 includes the limitation "a formulation ... bridging from one edge or surface to another." Thus, each of the independent claims includes the limitation that the coating bridges from an edge or surface to another edge or surface.

Bridging and coating have two different meanings, as evidenced by the specification on page 7, lines 14-20:

A "scaffold" is a substrate configured to have adjacent edges or surfaces in close proximity to each other so that the coating material, when applied, *will not only coat the surfaces but will **bridge** from one surface to the other*. For example, a scaffold may be provided by a wire configured into a coil having open windings. When the polymer coating is applied to the scaffold, it *not only covers the surface of the wire but also **bridges** from one winding to the next* so that the *finished device may have the shape of a cylinder with the coiled wire scaffold embedded therein*. (emphasis added here)

That is, the text contrasts "bridging" with "coating", clarifying that "bridging" and "coating" are not synonymous. "Coating" has the meaning of covering a surface, i.e., the surface supports the coating material. By contrast, "bridging" has the meaning of spanning the gap between two separated edges or surfaces; i.e., where the coating material "bridges", it is unsupported by an edge or surface. In this example, the text describes the "bridging" by the polymer coating as the polymer coating spanning the distance from one winding of the coil to the next so that the device has the shape of a cylinder, and not of a helical coil.

Whether a material "bridges" two surfaces is independent of whether the material "continuously coats" each of the surfaces. That is, there are at least four possible configurations of a coating material and two separated surfaces:

- The material does not continuously cover either surface and does not "bridge", i.e., span, the gap between them.
- The material continuously covers each surface, but does not "bridge" the gap between them.

- The material is in contact with each surface and "bridges" the gap between them, but the material does not continuously cover either surface, i.e., the material merely contacts part of each surface.
- The material continuously covers each surface and "bridges" the gap between them.

Whitbourne '483 cannot and does not describe a "coating ... bridging from one edge or surface to another," a limitation of each of claims 23, 61, 68, 43, and 45. Similarly, Whitbourne '483 cannot and does not describe a "formulation bridging from one edge or surface to another," a limitation of claim 50. In item 4 on page 3 of the 2006 Action, the Examiner concedes that Whitbourne '483 is "silent to the specific design of the substrates regarding their edges and surfaces." Given that Whitbourne '483 does not describe edges and surfaces of substrates, Whitbourne '483 cannot and does not describe a "coating ... bridging from one edge or surface to another."

The Examiner continues in item 4 by stating that the coating of Whitbourne '483 is "a continuous coating over each surface." Whether or not the coating of Whitbourne '483 is "continuous" is irrelevant to the question of whether Whitbourne '483 renders independent claims 23, 61, 68, 43, 45, and 50 obvious. As discussed above, each of these claims include the limitation of "a coating ... bridging from one edge or surface to another." The claims do not require a continuous coating. Accordingly, whether a coating bridges (as is required by the claims of the above-identified application) is independent of whether the coating is continuous.

The Examiner invites Applicants "to provide evidence that the continuous coating of the invention does onto [sic] cover the edges and bridge surfaces." The relevance of the Examiner's "invitation" is unclear, and under the present 35 U.S.C. § 103(a) rejection, Applicant does not have the burden to provide such evidence.

In item 7 on page 4 of the 2006 Action, the Examiner states that "it would have been obvious to a skilled artisan to follow the suggestions of the art to produce a medical article with a continuous coating over all surfaces..." Any teaching or suggestion of producing a medical article with a continuous coating is simply irrelevant to the question of whether independent claims 23, 61, 68, 43, 45, and 50 meet the requirement of 35 U.S.C. § 103(a) or are obvious. As discussed above, each of these claims include the limitation of "a coating [or formulation]... bridging from one edge or surface

to another." Whitbourne '483 does not teach or disclose the "bridging" of a coating from one surface to another. Therefore, because Whitbourne '483 does not teach or suggest all the limitations, the Examiner has failed to establish a *prima facie* case of obviousness of independent claim 23, 61, 68, 43, 45, or 50, or of claims dependent therefrom.

**B. Lack of Suggestion or Motivation to Modify the Reference**

Because the Examiner fails to consider the limitation of "bridging from one edge or surface to another" in independent claims 23, 61, 68, 43, 45, and 50 of the above-identified application, the Examiner also fails to provide a suggestion or motivation for modifying the medical articles of Whitbourne '483 to a device which has such bridging. For this additional reason, the Examiner has failed to establish a *prima facie* case of obviousness of independent claim 23, 61, 68, 43, 45, or 50, or of claims dependent therefrom.

**II. Rejection of Claims 26-27, 53-55, 59, 60, 66-67, 72, and 73 over Whitbourne '483, Kamath '029, and Khan '120: Lack of Teaching or Suggestion of the "Bridging" Claim Limitation**

In items 8-12 on pages 4-5 of the 2006 Action, the Examiner rejects claims 26-27, 53-55, 59, 60, 66-67, 72, and 73 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of Whitbourne '483, U.S. Patent Number 6,335,029 to Kamath et al. ("Kamath '029"), and U.S. Patent Number 5,589,120 to Khan et al. ("Khan '120").

None of the Whitbourne '483, Kamath '029, and Khan '120 references present a coating material "bridging" from one surface or edge to another. By contrast, as discussed in I.A. above, independent claims 61, 50, and 23, and claims dependent therefrom, include the limitation of "bridging from one edge or surface to another." Whether or not "[a] skilled artisan would have been motivated to continuously coat the coil as taught by '483," as the Examiner alleges in item 12 on page 5 of the 2006 Action, is irrelevant and has no bearing on whether the material bridges between two separate surfaces or edges. For example, a material can continuously coat each of two surfaces without bridging between the surfaces. Because the combination of Whitbourne '483, Kamath '029,

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Following Office Action of March 2, 2006

and Khan '120 does not teach or suggest all the limitations of each of independent claims 61, 50, and 23, and claims dependent therefrom, the Examiner has failed to establish a *prima facie* case of obviousness of claims 26-27, 53-55, 59, 60, 66-67, 72, and 73. *See* MPEP § 2142.

Furthermore, the Examiner does not provide any specific motivation to combine Whitbourne '483, Kamath '029, or Khan '120. Therefore, even if the combination of these references would teach all of the limitations of one or more of the claims of the above-identified application, the Examiner has not established a *prima facie* case of obviousness of any claim of the above-identified application.

Indeed, as presented on pages 13-15 of Applicants' July 1, 2005 response, because the energy associated with the gas plasma treatment could act to disrupt the structure of a coating that bridges, Kamath '029 teaches away from the independent and dependent claims of the above-identified application. Neither the Whitbourne '483 nor the Kamath '029 patent mentioned the range of diffusion taught by the above-identified application and claimed in claims 31 and 45. Khan '120 also does not address the range of diffusion of a therapeutic agent of the device. These references would not be combined, and do not render the claimed invention obvious.

For the reasons presented above, all of the pending claims 23-74 should be allowed.

Respectfully submitted,



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Date: September 5, 2006

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